

REMARKS/ARGUMENT

In view of the past prosecution of the application, the claims have been studied and a serious effort has been made to redraft the claims to bring out the new and unobvious invention discovered by the inventors regarding the formulation and creation of a fat based composition that more closely parallels HMF and in a way that the cost of the of preparing infant formulae is much lower. As is well accepted, prior to the advent of the present invention the cost of infant formulae has been such that it is very difficult for economically disadvantaged families to take advantage of its availability. The purpose of the present invention is to provide a more nutritious fat composition, prevent constipation and stool hardening, prevent the formation of soaps, to prevent Ca absorption, to provide an equivalent of HMF that parallels Mother's Milk and is a viable mimetic, to provide sufficient palmitic fatty acid residue on the correct sn- position of the glycerol backbone, and to provide sufficient unsaturated fatty acids on the correct sn- position of the glycerol backbone, especially oleic fatty acid, and above all to achieve the above at the lowest possible cost.

The situation was akin to the time of Henry Ford. Automobiles were known and many different models were available. The problem was simply that all available models were too expensive for the "common man and woman". What Henry Ford discovered was a way to design and make an automobile, the model T, that served the purpose as well as existing models but was sufficiently lower in cost to become available to the "common man and woman". That is what the present invention has accomplished, a fat based composition that achieves all the above enumerated purposes at a substantially lower cost so that it is available to families lower on the economic scale.

This has been achieved by the invention expressed in the main composition claim as follows:

23. An edible enzymatically-prepared vegetable fat base composition; said composition comprising over 90% of a mixture of triglycerides in which mixture the total palmitic acid residues content is not more than 38% w/w of the total fatty acid residues of said triglycerides; from about 62% to about 70% of the total palmitic acid residues of said triglycerides are attached at the sn-2 position of the glycerol backbone of said triglycerides; at least 60% w/w of the fatty acid residues attached at the sn-2 position of

the glycerol backbone of said triglycerides are palmitic acid residues; at least 70% w/w of the fatty acid residues attached at the sn-1 and sn-3 positions of the glycerol backbone of said triglycerides are unsaturated fatty acid residues; and 6-17% w/w of the unsaturated fatty acid residues at the sn-1 and sn-3 positions of said triglycerides are linoleic acid residues; and 40-60% w/w of the unsaturated fatty acid residues at the sn-1 and sn-3 positions of said triglycerides are oleic acid residues.

As will be evident from the main claim 23, all the purposes expressed above are achieved by the specific limitations of the claimed combination. Support for every limitation of the main claim can be found in the specification, there is no new matter whatsoever. The limitations of the combination in new main claim 23 are expressed with definiteness and comply and are supported fully by the disclosure in the written specification and the written description requirements of the law and regulations are fully complied with.

The redrafting of the main claim and the amendment or cancellation of previous dependent claims overcomes previous rejections concerning Section 112.

Claims 1 to 6, 16, 17, and 20 to 22 have been canceled. New claims 23-24 have been added. Claims 7-8, 11, 13-15 and 18-19 have been amended. Claims 9-10 and 12 were previously presented. It is respectfully submitted that the amendments do not introduce any new subject matter.

Claim Rejections - 35 USC § 102 / 35 USC § 103

In the office action, canceled claims 1-4 were rejected as anticipated by, or in alternative as obvious over the publication Food Ingredients First Com, July 4, 2003, previously made of record. Briefly, it was contended that the article teaches the enzymatically prepared fat base composition called InFat. It was further contended that the article teaches that InFat is exclusive oil with a triglycerides composition, designed to have higher palmitic acid content at the correct position of the triglycerides and teaches that up to 90% of the total palmitic acid in InFat is located at the sn-2 position of the triglyceride. It was also contended that the article teaches InFat product(s) will necessarily comprise the claimed saturated and unsaturated fatty acids in the claimed ranges or concentrations even without any specific disclosure in the article to support this contention. Further, it was contended that it would have been reasonably expected

by one of ordinary skill in the art that a teaching of InFat in the art, without any specific disclosure of its composition, would have comprised the specific fatty acid residues in amounts that would meet the claimed ranges or amounts. Such contentions are absurd and not based on any facts.

InFat is a Registered trademark No. **3492620** that simply designates the origin of products made by Enzymotec Limited and sold in the commercial marketplace and do not designate nor define any particular product or its content. See details of the registration of the InFat trademark set forth below. Thus, as it is admitted in the Official Action that no details of the composition are given in the article, it cannot and does not by law anticipate the claimed combination invention as set forth in the specifically claimed limitations of the main claim.

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| Word Mark | INFAT |
| Goods and Services | IC 001. US 001 005 006 010 026 046. G & S: Chemicals, namely, oil and fats that mimic breast milk used in the manufacture of dietary supplements, functional foods, nutraceuticals, food products and beverages, edible oils, edible fats, flour, and non-alcoholic drinks IC 005. US 006 018 044 046 051 052. G & S: Oil and fat structures that mimic breast milk sold as an integral component for use in dietetic food, food additives adapted for medical uses, and food for infants IC 029. US 046. G & S: Oil and fat structures that mimic breast milk sold as an integral component for edible oils and fats, milk and dairy products excluding ice cream, ice milk and frozen yogurt, soy products, namely, soy-based snack foods, soy-based proteins, soy-based food bars, soy-based milk substitutes, canned food, namely meat, fruit, vegetables, milk, and milk substitutes, and yogurt |
| Standard Characters Claimed | |
| Mark Drawing Code | (4) STANDARD CHARACTER MARK |
| Serial Number | 78625241 |
| Filing Date | May 9, 2005 |
| Current Filing Basis | 44E |
| Original Filing Basis | 1B;44D |
| Published for Opposition | July 17, 2007 |
| Registration Number | 3492620 |
| Registration Date | August 26, 2008 |

The claims were also rejected as being unpatentable over US Patent No. 4,876,107 (King et al.) in view of Innis et al. (American Institute of Nutrition, 1995), both previously made of record. King et al describes and claims a rearranged vegetable fat composition. The rearrangement is of a top fraction of palm oil with either oleic acid or an alternative fatty acid composition consisting of palmitoleic, stearic, oleic linoleic and others. The top fraction was 80% P₃ and 20% POP (Palmitic, Oleic and Palmitic). The palm top fraction was melted with oleic acid and dissolved in hexane (an organic solvent). The catalyst for rearrangement was *Mucor Miehei* lipase enzyme. King et al did not provide any other disclosure of how it might control the resulting triglyceride fraction obtained. The resulting triglycerides are supposedly set forth in Table 4, but without any clarification of what the symbols mean, so it is indefinite and unclear what resulted. As shown in table 5 and 6 the triglyceride fractions include lauric and myristic fatty acid residues. Table 7 shows NMR results, but the significance of these results vis-à-vis the present invention is irrelevant. Clearly King does not show the limitations expressed in the combination claimed in the main composition claim set forth above.

What King et al teaches is clearly set forth in his claims. King et al teaches that at least half of fatty acid residues at the sn-2 position of the glycerol backbone are palmitic acid residues (with the rest unspecified) and randomly distributed between the sn-1 and sn-3 positions are unsaturated fatty acid residues and no more saturated fatty acid residues than in the sn-2 position.

What King et al teaches is to use hexane and a catalyst to rearrange top palm oil with oleic acid. Whatever King et al gets with his method is expressed in his claims, namely the use of excessive palmitic acid with at least 50% at the sn-2 position. King et al does not teach or suggest the limitations of the claims to the present invention. More importantly, King et al does not disclose, teach or suggest that the palmitic acid residues content be reduced to below at most 38% of the total fatty acids of the triglycerides, nor does King et al. disclose, teach or suggest that 62% w/w to 70% w/w of the total palmitic residues be attached on the sn-2 position, nor does King et al.

disclose, teach or suggest that at least 60% w/w of the fatty acid residues attached at the sn-2 position be palmitic fatty acid residues. King et al. does not disclose, teach or suggest that the vegetable fat composition be enzymatically derived. There are other limitations in the main claim that also are not met by King et al.

It is respectfully submitted that none of the Examples provided in King *inter-alia* Sample 3 of Table 1 disclose the presently claimed fat base composition combination with all the limitations expressed in the main combination claim.

Regarding Innis, this publication is non-analogous art, deals with milk fatty acids and how the body absorbs palmitic acid from the sn-2 position. This article is educational but offers nothing regarding how one can create a HMF that emulates Mother's milk fat. Everyone has known the targets for a long, long time, but no one has successfully created a vegetable fat composition that has the necessary attributes while avoiding the detrimental attributes and achieving a product with a substantially lower cost. That is what this invention is all about; providing a successfully created vegetable fat composition with the necessary ;positive attributes and achieving a product having a substantially lower cost.

There is no motivation or way to combine King et al and Innis publication; they are dichotomous. A person versed in the art of making mimetic of HMF would gain nothing from this dichotomous combination of references. King et al method and product and Innis's description of how palmitic acid is absorbed by the body offers no suggest how to make a mimetic other than to try to match HMF. That is what King et al tried to do.

Further, the Applicant wishes to note that a main object of the instant invention is not merely to provide human milk fat approximates, but to provide cost-effective approximates that can be used as mimetic substitutes of human milk fat in infant foods, particularly formulas as set forth in paragraphs [0034] and [0098] of the published application US2007/0218169. It is noted that the cost-effectiveness of the present invention is realized while maintaining higher quality of the final product and better health for the consuming infant.

A person versed in the art would have the normal expectation that a concentrate with palmitic acid content lower than the samples provided by King et al would result in a lower quality substitute human milk fat. Although the concentrate (fat base) of the instant invention as currently claimed is characterized by lower palmitic acid content, not more than 38% with respect to King et al $\geq 40\%$, the inventors of the instant application had surprisingly found that less palmitic acid content can be successfully used to obtain a substituted human milk fat with the more desired beneficial characteristics of human milk, see Example 1 and Table 1 in the specification.

To further substantiate the patentability of the presently claimed invention over King et al, Applicants submit the following calculations illustrating the advantages of the claimed fat bases in term of both costs and quality:

Human milk is considered to be the best nutrition for infants. Ingredients for infant formulas mimicking human milk are being constantly developed. Infant formulae producers make significant efforts in looking for ingredients that will bring their formulae closer in composition and properties to human milk. However, infant formula producers must also take into account the cost of mass production and the cost to the final customer.

The main saturated fatty acid in human milk fat is palmitic acid, constituting 17-25% of total fatty acids, of which over 70% are esterified to sn-2 position of the glycerol backbone.

Currently, there are three options for infant formula fat fractions on the market:

Option 1: Standard vegetable oil mix (palm oil and other oils) providing the high palmitic acid content as in human milk but mainly esterified at the sn-1 and sn-3 positions.

Option 2: Vegetable oil mix without palm oil providing low palmitic acid content.

Option 3: Beta-palmitate products providing high palmitic acid content mainly at the sn-2 position as in human milk. Those products are based on vegetable oils but require special fats and an enzymatic step to structure the triglyceride resulting in high sn-2 palmitic acid content.

Option 3 is the fat fraction composition which is the best human milk fat mimetic. Beta-palmitate allows the infant optimal digestion, as similar as possible to human breast milk, by reducing stool hardness, reducing formation of calcium soaps and enhancing fat absorption and fat recovery. However, this option is the most expensive, due to the enzymatic processes required to structure a major part of the palmitic acid residues at the sn-2 position prior to the blending with vegetable oils.

In the United States market, only products prepared by using Options 1 and 2 are used, mainly due to cost considerations. In the European market, products on the basis of Option 3 are used for premium high cost formulas only, whereas products according to Option 1 are the most common due to cost considerations.

The current application provides a beta-palmitate type of product which is more cost-effective in comparison to other similar products defined under Option 3 e.g., samples of Table 1 of King et al. As stated above, the fat bases of the instant application are distinct from the concentrates of King et al. The differences provide cost-wise advantages with respect to the final products, in terms of amount of concentrate needed to prepare the blend, which is the human milk fat mimetic comprised in the infant formula (e.g., note Example 2 and Table 1 of the instant application) and at the same time achieving similarity of the final product to human milk fat.

The following calculation is based on a ratio of 5:1 fat base (of the invention) cost compared to other vegetable oils cost, and on the known cost of 1-2\$ per 1 Kg of vegetable oil. Accordingly, an estimated cost of fat base would be 5-10\$ per kg. Thus, calculated costs of blends (fat fractions for infant formula) are as follows:

- using 30% fat base of the present invention and 70% other vegetable oils would result in production cost of 2.2-4.4\$ per 1Kg of mixture (blend).
- using 50% fat base of the present invention and 50% other vegetable oils would result in production cost of 3-6\$ per 1Kg of mixture (blend).
- using 70% fat base of the present invention and 30% other vegetable oils would result in production cost of 3.8-7.6\$ per 1Kg of mixture (blend).

The above calculations illustrate that the costs involved when using 50% fat base or 70% fat base, as for example presented in King (see Table 2 of King) are 36% or even 72% higher compared to using only 30% fat base.

Thus, as can be seen in Table 1 of the present application, the ratio (% of sn-2 palmitic acid of total palmitic acid normalized per position) is about 74.6. The ration is an industry standard of the value of the fat composition. This high value of 74.6 is characteristic of human milk fat. As noted in the Official Action, the samples of King et al present a ratio of about 66-67. In contrast, as can be seen from Table 1 of the present application, the claimed composition has a ratio of up to 70, although its total palmitic acid content is lower (32 vs. 40 to 44.5) than that of King. This is an unexpected result (advantage). In terms of both properties and cost, the advantages of the fat base of the invention are remarkable, and could not be arrived at from King et al alone or combined with any of the other cited references.

With respect to Cooper (US 5371253), this patent does not deal with the problem solved by the present invention and clearly is non-analogous art. Cooper is only concerned with producing esterified alkoxyated mono- and diglycerides suitable for use in a reduced calorie fat substitute in food products. Cooper teaches nothing regarding a mimetic for HMF.

As is evident from the above amended and new claims presented herein and the remarks and argument, the claims as present in this amendment clearly are patentable over the cited and applied references. Accordingly, it is earnestly solicited that the application be reconsidered and the claims presented herein be deemed allowable.

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7056-X08-021).

Respectfully submitted,

A handwritten signature in black ink that reads "Martin Fleit". The signature is written in a cursive, flowing style.

Martin Fleit, Reg. #16,900

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